

XANAX- alprazolam 0.5mg tablet
Advanced Rx Pharmacy of Tennessee, LLC

Alprazolam 0.5mg tablets #60

Medication Guide Section

MEDICATION GUIDE

Alprazolam (al pra' zoe lam) Tablets, USP C-IV

What is the most important information I should know about alprazolam tablets?

Alprazolam tablets are a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.

Alprazolam tablets can make you sleepy or dizzy, and can slow your thinking and motor skills.

Do not drive, operate heavy machinery, or do other dangerous activities until you know how alprazolam tablets affect you.

Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking alprazolam tablets without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, alprazolam tablets may make your sleepiness or dizziness much worse.

Do not take more alprazolam tablets than prescribed.

What are alprazolam tablets?

Alprazolam tablets are a prescription medicine used:

to treat anxiety disorders

for the short-term relief of the symptoms of anxiety

to treat panic disorder with or without a fear of places and situations that might cause panic, helplessness, or embarrassment (agoraphobia)

Alprazolam tablets are a federal controlled substance (C-IV) because they can be abused or lead to dependence. Keep alprazolam tablets in a safe place to prevent misuse and abuse. Selling or giving away alprazolam tablets may harm others, and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.

It is not known if alprazolam tablets are safe and effective in children.

Elderly patients are especially susceptible to dose related adverse effects when taking alprazolam tablets.

It is not known if alprazolam tablets are safe and effective when used to treat anxiety disorder for longer than 4 months.

It is not known if alprazolam tablets are safe and effective when used to treat panic disorder for longer than 10 weeks.

Do not take alprazolam tablets if:

you are allergic to alprazolam, other benzodiazepines, or any of the ingredients in alprazolam tablets.

See the end of this Medication Guide for a complete list of ingredients in alprazolam tablets.

you are taking antifungal medicines including ketoconazole and itraconazole

Before you take alprazolam tablets, tell your healthcare provider about all of your medical conditions, including if you:

have or have had depression, mood problems, or suicidal thoughts or behavior

have liver or kidney problems

have lung disease or breathing problems

are pregnant or plan to become pregnant. Alprazolam may harm your unborn baby. You and your healthcare provider should decide if you should take alprazolam tablets while you are pregnant. are breastfeeding or plan to breastfeed. Alprazolam passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take alprazolam tablets. You should not breastfeed while taking alprazolam tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking alprazolam tablets with certain other medicines can cause side effects or affect how well alprazolam tablets or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

How should I take alprazolam tablets?

See “What is the most important information I should know about alprazolam tablets?”

Take alprazolam tablets exactly as your healthcare provider tells you to take them. Your healthcare provider will tell you how many alprazolam tablets to take and when to take them.

If you take too many alprazolam tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking alprazolam tablets?

Alprazolam tablets can cause you to be drowsy. Do not drive a car or operate heavy machinery until you know how alprazolam tablets affect you.

You should not drink alcohol while taking alprazolam tablets. Drinking alcohol can increase your chances of having serious side effects.

What are the possible side effects of alprazolam tablets?

Alprazolam tablets may cause serious side effects, including:

See “What is the most important information I should know about alprazolam tablets?”

Abuse and dependence. Taking alprazolam tablets can cause physical and psychological dependence.

Physical and psychological dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.

Withdrawal symptoms. You may have withdrawal symptoms if you stop taking alprazolam tablets suddenly. Withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your healthcare provider about slowly stopping alprazolam tablets to avoid withdrawal symptoms.

Seizures. Stopping alprazolam tablets can cause seizures and seizures that will not stop (status epilepticus).

Mania. Alprazolam tablets may cause an increase in activity and talking (hypomania and mania) in people who have depression.

The most common side effects of alprazolam tablets include drowsiness and light-headedness. These are not all the possible side effects of alprazolam tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store alprazolam tablets?

Store alprazolam tablets between 68°F to 77°F 20°C to 25°C

Keep alprazolam tablets and all medicines out of the reach of children.

General information about the safe and effective use of alprazolam tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

Do not use alprazolam tablets for a condition for which they were not prescribed.

Do not give alprazolam tablets to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about alprazolam tablets that is

written for health professionals. For more information call Actavis at 1-888-838-2872.

What are the ingredients in alprazolam tablets?

Active ingredient: alprazolam, USP

Inactive ingredients: colloidal silicon dioxide, corn starch, docusate sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium benzoate. The 0.5 mg tablet also contains FD&C yellow #6 aluminum lake (sunset yellow lake). The 1 mg tablet also contains FD&C blue #2 aluminum lake. The 2 mg tablet also contains D&C yellow #10 aluminum lake.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Indications and Usage Section

INDICATIONS AND USAGE

Anxiety Disorders

Alprazolam tablets, USP are indicated for the management of anxiety disorder (a condition corresponding most closely to the APA Diagnostic and Statistical Manual [DSM-III-R] diagnosis of generalized anxiety disorder) or the short-term relief of symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.

Generalized anxiety disorder is characterized by unrealistic or excessive anxiety and worry (apprehensive expectation) about two or more life circumstances, for a period of 6 months or longer, during which the person has been bothered more days than not by these concerns. At least 6 of the following 18 symptoms are often present in these patients: Motor Tension (trembling, twitching, or feeling shaky; muscle tension, aches, or soreness; restlessness; easy fatigability); Autonomic Hyperactivity (shortness of breath or smothering sensations; palpitations or accelerated heart rate; sweating, or cold clammy hands; dry mouth; dizziness or light-headedness; nausea, diarrhea, or other abdominal distress; flushes or chills; frequent urination; trouble swallowing or 'lump in throat'); Vigilance and Scanning (feeling keyed up or on edge; exaggerated startle response; difficulty concentrating or 'mind going blank' because of anxiety; trouble falling or staying asleep; irritability). These symptoms must not be secondary to another psychiatric disorder or caused by some organic factor.

Anxiety associated with depression is responsive to alprazolam.

Panic Disorder

Alprazolam tablets, USP are also indicated for the treatment of panic disorder, with or without agoraphobia.

Studies supporting this claim were conducted in patients whose diagnoses corresponded closely to the DSM-III-R/IV criteria for panic disorder (see CLINICAL STUDIES).

Panic disorder (DSM-IV) is characterized by recurrent unexpected panic attacks, i.e., a discrete period of intense fear or discomfort in which four (or more) of the following symptoms develop abruptly and

reach a peak within 10 minutes: (1) palpitations, pounding heart, or accelerated heart rate; (2) sweating; (3) trembling or shaking; (4) sensations of shortness of breath or smothering; (5) feeling of choking; (6) chest pain or discomfort; (7) nausea or abdominal distress; (8) feeling dizzy, unsteady, lightheaded, or faint; (9) derealization (feelings of unreality) or depersonalization (being detached from oneself); (10) fear of losing control; (11) fear of dying; (12) paresthesias (numbness or tingling sensations); (13) chills or hot flushes.

Demonstrations of the effectiveness of alprazolam by systematic clinical study are limited to 4 months duration for anxiety disorder and 4 to 10 weeks duration for panic disorder; however, patients with panic disorder have been treated on an open basis for up to 8 months without apparent loss of benefit. The physician should periodically reassess the usefulness of the drug for the individual patient.

Principal Display Panel



XANAX

alprazolam 0.5mg tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:80425-0099(NDC:0228-2029)
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALPRAZOLAM (UNII: YU55MQ3IZY) (ALPRAZOLAM - UNII: YU55MQ3IZY)	ALPRAZOLAM	0.5 mg

Product Characteristics

Color	orange	Score	2 pieces
Shape	ROUND	Size	7mm
Flavor		Imprint Code	R;029
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0099-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/1993	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA074342		10/01/1993	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment			
Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0099)